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Acacia Pharma Plans to Resubmit the BARHEMSYS® NDA in Q3 2019

This announcement contains inside information for the purposes of Article 7 of the Market Abuse Regulation (EU) No 596/2014.

Cambridge, UK and Indianapolis, US – 8 July 2019: Acacia Pharma Group plc ("Acacia Pharma" or "the Company"), a pharmaceutical company developing and commercialising hospital products for US and international markets, announces receipt of the official Type A meeting minutes from the US Food and Drug Administration ("FDA") relating to the Company's BARHEMYS® (amisulpride injection) New Drug Application ("NDA"). At this meeting, Acacia Pharma agreed with FDA a plan to resubmit the NDA, designating a new supplier of amisulpride, the active pharmaceutical ingredient ("API") in BARHEMSYS.

The new supplier has extensive experience both in manufacturing amisulpride and in producing APIs to the standards required by FDA. The supplier has also successfully undergone regular inspections by regulatory authorities for compliance with current Good Manufacturing Practices ("cGMP"), most recently by FDA in September 2018 when its facility was rated "No Action Indicated" ("NAI"), the best possible outcome. Approximately 60% of the supplier's production is currently destined for the US market, including the APIs for a number of products for intravenous and other parenteral use. Acacia Pharma began qualifying the new amisulpride supplier in October 2018.

"We are pleased with the constructive and productive meeting we had with FDA and now have a clear path to resubmit the BARHEMSYS NDA in the third quarter of this year. We expect a six-month review by the FDA, which would give a projected PDUFA (Prescription Drug User Fee Act) date in the first quarter of 2020," said Dr Julian Gilbert, CEO of Acacia Pharma. "The supplier has an excellent track record of manufacturing API for FDA-approved products and, importantly, of passing cGMP inspections, including an FDA inspection less than a year ago. Our commercial team is continuing pre-launch activities and we look forward to bringing BARHEMSYS to the market as soon as possible."

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About Acacia Pharma

Acacia Pharma is a hospital pharmaceutical company focused on the development and commercialisation of new nausea & vomiting treatments for surgical and cancer patients. The Group has identified important and commercially attractive unmet needs in nausea & vomiting and has discovered two product candidates based on the same active ingredient, amisulpride, to meet those needs.

The Group's lead project, BARHEMSYS® for post-operative nausea & vomiting (PONV), has generated positive results in four Phase 3 clinical studies. Its sister project, APD403 for chemotherapy induced nausea & vomiting (CINV), has successfully completed one proof-of-concept and one Phase 2 dose-ranging study in patients receiving highly emetogenic chemotherapy.

Acacia Pharma is based in Cambridge, UK and its US operations are centred in Indianapolis, IN. The Company is listed on the Euronext Brussels exchange under the under ISIN code GB00BYWF9Y76 and ticker symbol ACPH. www.acaciapharma.com

Forward looking statement

This announcement includes forward-looking statements, which are based on current expectations and projections about future events. These statements may include, without limitation, any statements preceded by, followed by or including words such as "believe", "expect", "intend", "may", "plan", "will", "should", "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements may and often do differ materially from actual results. These forward-looking statements are subject to risks, uncertainties and assumptions about the Company and its subsidiaries and investments, including, among other things, the development of its business, trends in its operating industry, and future capital expenditures and acquisitions. By their nature, forward-looking statements involve risk and uncertainty because they relate to future events and circumstances. Any forward-looking statements reflect the Company's current view with respect to future events and are subject to risks relating to future events and other risks, uncertainties and assumptions relating to the Group's business, results of operations, financial position, prospectus, growth or strategies and the industry in which it operates. Save as required by law or applicable regulation, the Company and its affiliates expressly disclaim any obligation or undertaking to update, review or revise any forward-looking statement contained in this announcement whether as a result of new information, future developments or otherwise. Forward-looking statements speak only as of the date they are made.